REMARKS

Claims 86-96 and 101-123 are pending. Claims 91, 106, 112, 114, and 115 have been withdrawn by the Examiner. Claims 86 and 101 have been amended and claims 97-100 have been canceled without prejudice or disclaimer. Claims 116-123 are new. Support for the claim amendments and new claims can be found in the application as filed, for example, at page 11, lines 23-26; page 74, lines 11-14; and page 85, lines 21-23. No new matter has been added.

Applicants understand that upon allowance of a generic claim (e.g., claim 86 and/or claim 101), withdrawn claims that depend from or otherwise incorporate all the limitations of an allowable generic claim will be re-entered and considered in the present application.

Claim Objection

The Office at page 3 of the Office Action objects to claim 101 for the recitation of "an amino acid sequence that comprises an amino acid sequence that is at least 95% identical to SEQ ID NO:2."

As indicated in the claim amendments presented herein, claim 101 has been amended as suggested by the Office. Withdrawal of this objection is respectfully requested.

35 U.S.C. § 112, Second Paragraph

Applicants thank the Examiner for withdrawing the previously-raised indefiniteness rejection.

Claims 86-90, 92-96, 98, 101-105, 107-111, and 113. At page 4 of the Office Action, the Office alleges that claims 86-90, 92-96, 98, 101-105, 107-111, and 113 are indefinite for the recitation of "the sulfatase is an activated form of an endogenous sulfatase" and "the Formylglycine Generating Enzyme is an activated form of an endogenous Formylglycine Generating Enzyme."

In the interest of expediting prosecution, claims 86 and 101 have been amended and no longer recite these terms. Applicants respectfully request that this rejection of claims 86-90, 92-96, 98, 101-105, 107-111, and 113 be withdrawn.

Claims 101-105, 107-111, and 113. At page 5, the Office alleges that claims 101-105, 107-111, and 113 are indefinite in the recitation of "stringent conditions (6X SSC at 65°C)."

To expedite prosecution, this term is no longer recited in claim 101. Withdrawal of this rejection of claims 101-105, 107-111, and 113 is respectfully requested.

35 U.S.C. § 101

The Office rejects claims 86-90, 92-96, 98, 101-105, 107-111, and 113 as allegedly being drawn to non-statutory subject matter for reciting products of nature (Office Action at page 5).

As amended, claims 86 and 101 recite a sulfatase producing cell that, *inter alia*, expresses a sulfatase, wherein the sulfatase is an endogenous sulfatase that is activated by insertion of a strong promoter or an exogenous sulfatase, and a Formylglycine Generating Enzyme, wherein the Formylglycine Generating Enzyme is an endogenous Formylglycine Generating Enzyme that is activated by insertion of a strong promoter or an exogenous Formylglycine Generating Enzyme.

As these amendments make clear, the cells in claims 86 and 101 express an endogenous sulfatase or Formylglycine Generating Enzyme activated via insertion of a strong promoter or an exogenous sulfatase or Formylglycine Generating Enzyme. Such cells are not products of nature. For at least these reasons, Applicants respectfully request that this rejection of claims 86-90, 92-96, 98, 101-105, 107-111, and 113 be withdrawn.

35 U.S.C. § 112, First Paragraph: Written Description

At pages 6-11, the Office maintains its rejection of claims 86-90, 92-96, 98, 101-105, 107-111, and 113, alleging that Applicants have failed to demonstrate possession of the subject matter recited therein.

Applicants respectfully disagree with the Office's position, e.g., for the reasons set forth in Applicants' previous Reply to Office Action. However, in the interest of expediting prosecution, Applicants have amended claims 86 and 101 to recite, *inter alia*:

a cell that expresses a Formylglycine Generating Enzyme, wherein the Formylglycine Generating Enzyme is an endogenous Formylglycine Generating Enzyme of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78, wherein the endogenous Formylglycine Generating Enzyme is activated by insertion of a strong promoter, or an exogenous Formylglycine Generating Enzyme of amino acids 34-374 of

SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78 (claim 86) and

a cell that expresses an endogenous Formylglycine Generating Enzyme, wherein the endogenous Formylglycine Generating Enzyme is activated by insertion of a strong promoter, or an exogenous Formylglycine Generating Enzyme, the Formylglycine Generating Enzyme having: an amino acid sequence that comprises an amino acid sequence that has at least 95% identity to the amino acid sequence of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78 (claim 101).

As the Office recognizes at page 8 of the Office Action, the application as filed discloses SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78 as examples of the claimed Formylglycine Generating Enzyme. The application also discloses the amino acid sequence of amino acids 34-374 of SEQ ID NO:2 as an example of the claimed Formylglycine Generating Enzyme (see, e.g., page 74, lines 11-14 and page 85, lines 21-23 of the application as filed). For at least this reason, Applicants submit that possession of the subject matter recited in claims 86 and 101 is clear and respectfully request that this rejection of claims 86-90, 92-96, 98, 101-105, 107-111, and 113 be withdrawn.

35 U.S.C. § 112, First Paragraph: Enablement

Applicants thank the Office for stating at page 11 that the application enables a sulfatase-producing cell transformed with an expression vector encoding a sulfatase polypeptide and encoding the FGE polypeptide of SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78, wherein the FGE polypeptide modifies a catalytic cysteine to a formylglycine of the sulfatase.

However, the Office at pages 11-18 maintains its rejection of claims 86-90, 92-96, 98, 101-105, 107-111, and 113 as allegedly lacking enablement.

Applicants respectfully disagree with the Office's rejection and submit that the claims are enabled by the application as filed, e.g., for the reasons set forth in Applicants' previous Reply to Office Action.

However, to expedite prosecution, claims 86 and 101 have been amended, as discussed above. Applicants submit that the amendments overcome the Office's rejection and respectfully request withdrawal of the same.

35 U.S.C. § 102/103

Szameit et al. (J. Biol. Chem. 274:15375-15381 (1999); "Szameit"). The Office maintains its rejection and alleges that claims 86-90, 92, 101-105, and 107 are anticipated, or rendered obvious, by Szameit, as evidenced by Fang et al. (*J. Biol. Chem.* 279:14570-14578 (2004); "Fang") and GenBank Accession No. AJ131525.

Applicants respectfully disagree with the Office's position. Applicants submit that Szameit fails to offer any teaching or suggestion regarding a Formylglycine Generating Enzyme of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78, or a Formylglycine Generating Enzyme having at least 95% identity thereto.

In particular, Szameit fails to teach or suggest a cell that expresses, *inter alia*, a Formylglycine Generating Enzyme, wherein the Formylglycine Generating Enzyme is an endogenous Formylglycine Generating Enzyme of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78, wherein the endogenous Formylglycine Generating Enzyme is activated by insertion of a strong promoter, or an exogenous Formylglycine Generating Enzyme of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78 (claim 86).

Szameit also fails to teach or suggest a cell that expresses, for example, an endogenous Formylglycine Generating Enzyme, wherein the endogenous Formylglycine Generating Enzyme is activated by insertion of a strong promoter, or an exogenous Formylglycine Generating Enzyme, the Formylglycine Generating Enzyme having: an amino acid sequence that comprises an amino acid sequence that has at least 95% identity to the amino acid sequence of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78 (claim 101).

Fang and GenBank Accession No. AJ131525 do not remedy these deficiencies.

For at least this reason, Applicants submit that claims 86-90, 92, 101-105, and 107 are novel and non-obvious in light of Szameit and respectfully request that this rejection be withdrawn.

Rommerskirch et al. (Proc. Natl. Acad. Sci USA 89:2561-2565 (1992); "Rommerskirch"). The Office maintains its rejection and alleges that claims 86-90, 93-96, 98, 101-105, 108-111, and 113 are anticipated, or rendered obvious, by Rommerskirch, as evidenced by Dierks et al. (*Cell* 113:435-444 (2003); "Dierks") and Wraith et al. (*Human Genet.* 87:205-206 (1991); "Wraith").

Applicants respectfully disagree with the Office's position. Applicants submit that Rommerskirch fails to teach or suggest a cell that contains, *inter alia,* a Formylglycine Generating Enzyme, wherein the Formylglycine Generating Enzyme is an endogenous Formylglycine Generating Enzyme of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78, wherein the endogenous Formylglycine Generating Enzyme is activated by insertion of a strong promoter, or an exogenous Formylglycine Generating Enzyme of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78 (claim 86).

Further, Rommerskirch fails to teach or suggest a cell that contains, for example, an endogenous Formylglycine Generating Enzyme, wherein the endogenous Formylglycine Generating Enzyme is activated by insertion of a strong promoter, or an exogenous Formylglycine Generating Enzyme, the Formylglycine Generating Enzyme having: an amino acid sequence that comprises an amino acid sequence that has at least 95% identity to the amino acid sequence of amino acids 34-374 of SEQ ID NO:2, or SEQ ID NO:2, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, or 78 (claim 101).

Dierks and Wraith fail to remedy these deficiencies.

For at least these reasons, Applicants submit that claims 86-90, 93-96, 98, 101-105, 108-111, and 113 are not anticipated, or rendered obvious, by Rommerskirch. Withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that all of the pending claims are in condition for allowance, which action is expeditiously requested. Applicants do not concede any positions of the Examiner that are not expressly addressed above, nor do Applicants concede that there are not other good reasons for patentability of the presented claims or other claims.

A Request for Continued Examination is being filed herewith.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, please charge any deficiency to Deposit Account No. 50/2762.

Respectfully submitted,
von Figura et al., Applicants

By: /Natalie A. Lissy/
Natalie A. Lissy, Reg. No. 59,651
LANDO & ANASTASI, LLP
One Main Street
Cambridge, Massachusetts 02142
United States of America
Telephone: 617-395-7000
Facsimile: 617-395-7070

Docket No.: S2071-702810
Date: October 1, 2009